UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,905	03/05/2002	Robert L. Campbell	P-3250D1	7713

64154 7590 03/12/2007

DAVID W. HIGHET, VP & CHF. INTELLEC. PROP. COUNSEL
ANTONELLI, TERRY, STOUT & KRAUSE, LLP
BECTON DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER	
DEJONG, ERIC S	
ART UNIT	**PAPER NUMBER**
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/087,905	CAMPBELL ET AL.	
	Examiner	Art Unit	
	Eric S. DeJong	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *120-122, 124-126, 128 and 129* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *120-122, 124-126, 128 and 129* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/26/2007 has been entered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 120-122, 124-126, 128 and 129 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 120-122, 124-126, 128 and 129 are drawn to a computer program product and apparatus for identifying a culture medium component comprising identifying a predetermined set of test compounds, parameterizing said predetermined set of test compounds, performing a space-filling design, constructing a first test library, deriving a quantitative relationship between measured indicia and at least one parameter, identifying a candidate library of candidate culture media having an

estimated indicia that satisfies a test requirement, and identifying a second test library that contains candidate culture media. The above described computer program product and apparatus involves that applications of the above described abstract and algorithmic steps that results in an identification of a second test library of candidate culture media and, therefore, involves the application of a judicial exception. Regarding inventions involving the application of a judicial exception, said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation that results from said application of judicial exception, thus the Examiner must determine if said application of a judicial exception produces a useful, concrete, and tangible result.

In determining if the application of a judicial exception produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a result to be "useful," the application of a judicial exception must produce a result that is specific, and substantial. For a result to be "concrete," the application of a judicial exception must have a result that is reproducible. For a result to be "tangible," the application of a judicial exception must produce a real world result . Furthermore, the claim must be limited only to statutory embodiments.

Claims 120-122, 124-126, 128 and 129 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application of a judicial

exception to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the application of a judicial exception is outputted to a display, a user, a readily accessible memory or other computer on a network, or by including a physical transformation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 120-122 and128 are rejected under 35 U.S.C. 102(b) as being anticipated by Sen.

The instant claims are drawn to an apparatus for identifying a culture medium component comprising a means for identifying a predetermined set of test compounds, means for determining at least one parameter for each test compound, a means for performing a space-filling design of the parameterized predetermined set of test compounds, a means for constructing a first test library, a means for deriving a quantitative relationship between a measured indicia of a property to a least one parameter of a plurality of first test compounds, a means for identifying a candidate library containing a plurality of candidate culture media, wherein said candidate culture medium contains a respective test compound that is not in said first test library, and a

means for identifying a second test library containing culture media having a measured indicia that satisfies said test requirement.

[Claim 120-122 and 128]: Sen sets forth a method and related apparatuses for the optimization of the fermentation media for maximization of surfactin production (See Sen, Abstract), wherein the carbon source (glucose), the nitrogen source (ammonium nitrate), and the mineral salts ferrous and manganous sulphates were the critical components of the medium optimized (see also Sen, page 265, col. 2, lines 1-15). A 2^4 full factorial central composite experimental design was followed by multi-stage Monte-Carlo optimization was used in the design of experiments performed while allowing possible interactions between the four components (see Sen, page 264, col. 1, line 38 through page 265, col. 2, line 43). Surfactin was assayed by an indirect method which involved the measurement of surface tensions of diluted broth samples (see Sen, page 265, col. 1, lines 2035). Optimum values for the tested variables given maximal production of surfactant were determined from multiple rounds of media cultures that included model fitting in the form of Analysis of Variance (ANOVA), which involved developing a regression equation in accordance to Eq. (1) as well as deriving an empirical relationship in accordance with Eq. (2) (see page 265, col. 2, lines 1 through page 267, col. 2, line 15). Sen sets forth 4 compounds, Glucose, NH_2NO_3, $FeSO_4$, $MnSO_4$, relied upon in the disclosed optimization methods to determine optimal media conditions. In one embodiment the mutual effect of glucose and NH_2NO_3 on surfactin yield is determined (see for example Figure 2). In one embodiment the mutual effect of glucose and $FeSO_4$ on surfactin yield is determined (see for example Figure 2). In

another embodiment, the mutual effect of glucose and $MnSO_4$ on surfactin yield is determined (see for example Figure 3). In another embodiment, the mutual effect of NH_2NO_3 and $FeSO_4$ on surfactin yield is determined (see for example Figure 4). In another embodiment, the effect of NH_2NO_3 and $MnSO_4$ is determined (see for example Figure 5). Any pair of the above described combinations of experiments and optimization performed on sets of the 4 compounds (ie: Glucose, NH_2NO_3, $FeSO_4$, $MnSO_4$) read on the instantly claimed first and second test library as set forth in the instant claims. Sen further discloses the determination of the optimal concentration of components to arrive at a predicted media component, specifically the exact media formulation consisting of a mixture of glucose, ammonium nitrate, and ferrous and manganous sulphates (see page 269, col. 2, lines 16-31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 120-122, 124-126, 128 and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sen.

The instant claims are drawn to computer program product for identifying a culture medium component comprising a means for identifying a predetermined set of test compounds, means for determining at least one parameter for each test compound,

a means for performing a space-filling design of the parameterized predetermined set of test compounds, a means for constructing a first test library, a means for deriving a quantitative relationship between a measured indicia of a property to a least one parameter of a plurality of first test compounds, a means for identifying a candidate library containing a plurality of candidate culture media, wherein said candidate culture medium contains a respective test compound that is not in said first test library, and a means for identifying a second test library containing culture media having a measured indicia that satisfies said test requirement.

As discussed above, Sen sets forth the above described methods and related systems for the optimization of fermentation media for maximization of surfactin production. However, Sen does not fairly teach or disclose a computer product embodying a program of instruction executable for performing the disclosed method steps of Sen.

Regarding computer-related invention, the MPEP §2106(VI) states:

As is the case for inventions in any field of technology, assessment of a claimed computer-related invention for compliance with 35 U.S.C. 102 and 103 begins with a comparison of the claimed subject matter to what is known in the prior art. If no differences are found between the claimed invention and the prior art, the claimed invention lacks novelty and is to be rejected by Office personnel under 35 U.S.C. 102. Once distinctions are identified between the claimed invention and the prior art, those distinctions must be assessed and resolved in light of the knowledge possessed by a person of ordinary skill in the art. Against this backdrop, one must determine whether the invention would have been obvious at the time the invention was made. If not, the claimed invention satisfies 35 U.S.C. 103. Factors and considerations dictated by law governing 35 U.S.C. 103 apply without modification to computer-related inventions. Moreover, merely using a computer to automate a known process does not by itself impart nonobviousness to the invention. See In re Venner, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958). See also Dann v. Johnston, 425 U.S. 219, 227-30, 189 USPQ 257, 261 (1976).

Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to automate the disclosed methods for the optimization of fermentation media for maximization of surfactin production using computer readable medium holding computer readable code, since reliance on a computer to automate a known process does not by itself impart nonobviousness.

Response to Arguments

Applicant's arguments filed 01/26/2007 have been fully considered but they are not persuasive.

Regarding the previous rejection of claims over O'Shea, applicants argue that the examiner has not address Applicant's previous arguments traversing the rejections based on O'Shea.

In response, it is noted that on page 2, lines 3-5 of the Office action mailed 07/28/2006 that the rejection of claims 120-122, 124-126, 128, and 129 is withdrawn in view of amendments made to the claims as filed on 05/16/2006.

In regards to the rejection of claims over Sen, applicants argue that the previous Office action generally alleges that Sen sets forth a method for optimizing fermentation media for maximization of surfactin production without specifically identifying where Sen discloses each feature of the claimed invention.

In response, it is noted that page 2, line 6 through page 3, line 21 of the Office action mailed 07/28/2006 sets forth the basis of the instant rejection and cites as support specific references to Sen as support, which is further reiterated above in rejection.

Applicants further argue that the previous Sen does not perform a space-filling design with respect to any parameter for each test compound. Applicants further argue that Sen also teaches away from the instant invention by utilizing four test compounds in the culture media and that Sen also states "carrying out experiments with every possible factorial combination of test variables is impractical because of the large number of experiments that must be performed. Application cite Sen, page 264, lines 1-34 as support.

In response, it is first noted that Sen describes previous "classical method of media optimization" as involving changes in one variable at a time, and in this context states that "(o)n the other hand carrying out experiments with every possible factorial combination of the test variables is impractical because of the large numbers of experiments required" (see especially, page 264, col. 1, lines 27-34). Sen further teaches that on this point that the disclosed methodology relies on "a 2^4 full factorial central composite experimental design" (see especially page 264, col. 1, lines 34-36). In the instant case, the disclosed 2^4 full factorial composite design for four independent variable each at five levels with 8 star points and six replicates at the center points employed to fit a second order polynomial, (see especially Sen, page 265, col. 2, lines

43), provides a system that effectively covers a parameter space of possible media formulations and fairly reads on the instantly claims "space filling design". Further, neither the instant claims nor the instant specification set forth any definition for a "space filling design" that would exclude from the scope of the claims a 2^4 full factorial central composite experimental design for media conditions and composition as set forth by Sen. It is further noted that applicants response also refers to the factorial central composite experimental design method of Sen as a "space filling design" (see applicants response filed 01/26/2007, page 13, lines 1 and 4),

Applicants further argue that Sen's "space filling design" is actually performed on the concentration parameter of four different test compounds within the culture media in order to determine optimal concentrations and that Sen is completely silent about identification of new compounds based on the "space-filling design".

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the identification of new compounds based on a space-filling design) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). It is further noted, rather, that instant claim 128 recites "identifying a predetermined set of test compounds" (see line 3) and "means for performing a space-filling design of the parameterized predetermined set of test compounds to identify a plurality of first test compounds,

wherein said plurality of first test compounds is a subset of said predetermined set of test compounds" (see lines 7-10). Therefore the instantly claimed first test library generated by using the instantly claimed space-filling design is must only include "predetermined compounds" and is not limited to generating newly identified compounds as argued by applicants.

Applicants further argue that independent claim 128 requires derivation of a quantitative relationship between a measured indicia of a first culture media and at least one parameter of the first test compounds and that the claimed invention measures the same parameters in each of the predetermined sets of test compounds. Applicants further set forth that, in contrast, Sen measures a different parameter in each of the four compounds used and thus the regression formula applied by Sen would only correspond to those four test compounds and corresponding parameters. Applicants further argue that it is not possible for Sen to use this relationship to predict any information regarding unknown test compounds. Applicants further argue that Sen is completely silent on applying the derived relationship to predict values of unknown compounds.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., use a relationship to predict any information regarding unknown test compounds and predicting values of unknown compounds) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the

specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In the instant case, claim 128 recites "means for deriving a quantitative relationship between a measured indicia of a property of a plurality of first culture media and at least one parameter of said plurality of test compounds" (see lines 14-16). It is further reiterated from the instant rejection that surfactin was assayed by an indirect method which involved the measurement of surface tensions of diluted broth samples (see Sen, page 265, col. 1, lines 2035). Optimum values for the tested variables given maximal production of surfactant were determined from multiple rounds of media cultures that included model fitting in the form of Analysis of Variance (ANOVA), which involved developing a regression equation in accordance to Eq. (1) as well as deriving an empirical relationship in accordance with Eq. (2) (see page 265, col. 2, lines 1 through page 267, col. 2, line 15). As set forth in Table 2, the media samples we each evaluated using combination of variables, said variables comprising the concentrations of Glucose, NH_2NO_3, $FeSO_4$, $MnSO_4$, in the ANOVA analysis. Contrary to applicants argument, Sen derives a quantitative relationship between the property of surface tension in each of the broth solutions with respect to the combinations of the concentration of the above described compounds, which reads on deriving a quantitative relationship between a measured indicia of a property of a plurality of first culture media and at least one parameter of said plurality of test compounds as instantly claimed.

Applicants further argue that Sen is only able to vary the concentration of known media components and that it is not possible for Sen to predict any values

corresponding to components that are not in the first test library. Applicants further argue that Sen in completely silent on identifying a second test library.

It is reiterated from the above rejection that Sen sets forth 4 compounds, Glucose, NH_2NO_3, $FeSO_4$, $MnSO_4$, relied upon in the disclosed optimization methods to determine optimal media conditions. In one embodiment the mutual effect of glucose and NH_2NO_3 on surfactin yield is determined (see for example Figure 2). In one embodiment the mutual effect of glucose and $FeSO_4$ on surfactin yield is determined (see for example Figure 2). In another embodiment, the mutual effect of glucose and $MnSO_4$ on surfactin yield is determined (see for example Figure 3). In another embodiment, the mutual effect of NH_2NO_3 and $FeSO_4$ on surfactin yield is determined (see for example Figure 4). In another embodiment, the effect of NH_2NO_3 and $MnSO_4$ is determined (see for example Figure 5). Any pair of the above described combinations of experiments and optimization performed on sets of the 4 compounds (ie: Glucose, NH_2NO_3, $FeSO_4$, $MnSO_4$) read on the instantly claimed first and second test library as set forth in the instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDJ EDJ

2 March 2007

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER